



RECEIVED

JUL 17 2001

600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

HERMON-TAYLOR et al

Atty. Ref.: **117-319**

Serial No. **09/646,568**

Group: **1645**

Filed: **November 9, 2000**

Examiner:

For: **DIAGNOSTICS AND VACCINES FOR MYCOBACTERIAL
INFECTIONS OF ANIMALS AND HUMANS**

* * * * *

July 12, 2001

Assistant Commissioner for Patents
Washington, DC 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Supplemental to the Information Disclosure Statement filed May 9, 2001, the Examiner is requested to consider the attached copy of co-pending Application No. 09/705,911. Also attached is a copy of the pending claims of the co-pending Application No. 09/705,911. The Examiner is requested to return an initialed copy of the present paper as an indication of the consideration of the same.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____

B. J. Sadoff

Reg. No. **36,663**

BJS:eaw

1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

Claims of SN 09/705911
Filed Nov 6, 2000
Atty Ref 117-323 CLAIMS

1. A polypeptide in substantially isolated form which comprises a sequence selected from the sequences of Seq.ID.No: 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28 and 29, or a polypeptide substantially homologous thereto.

Cancelled
2. A polypeptide in substantially isolated form which comprises a sequence selected from the sequences of Seq.ID.No: 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28 and 29.

Cancelled
3. A polypeptide which comprises a fragment of a polypeptide defined in claim 1 or 2, said fragment comprising at least 12 amino acids and an epitope.

4. A polynucleotide in substantially isolated form which encodes a polypeptide according to any one of ~~claims 1 to 3~~ CLAIM 1

5. A polynucleotide in substantially isolated form which is capable of selectively hybridizing to Seq.ID.No: 3 or 4 or a fragment thereof.

6. A polynucleotide fragment according to claim 5 which comprises a sequence selected from the sequences of Seq.ID.No: 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25 and 27, or a polynucleotide at least 90% homologous thereto.

7. A polynucleotide in substantially isolated form comprising a sequence selected from the sequences of Seq.ID.No: 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25 and 27.

8. A polynucleotide probe which comprises a fragment of at least 15 nucleotides of a polynucleotide as defined in any one of ~~claims 4 to 7~~ CLAIM 1, optionally carrying a revealing label.

9. A recombinant vector carrying a polynucleotide as defined in ~~any one of claims 4 to 7~~. **CLAIM 5**

10. An antibody capable of binding a polypeptide or fragment thereof as defined in ~~any one of claims 1 to 3~~. **CLAIM 1**

11. An antibody capable of binding a polypeptide or fragment thereof wherein the polypeptide is a polypeptide which comprises a sequence selected from the sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or is a peptide substantially homologous thereto.

12. A test kit for detecting the presence or absence of a pathogenic mycobacterium in a sample which comprises a polynucleotide according to ~~any one of claims 4 to 8~~, a polypeptide according to ~~any one of claims 1 to 3~~, a polypeptide which comprises a sequence selected from the sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or a polypeptide substantially homologous thereto, or an antibody according to, ~~any one of claims 10 or 11~~. **CLAIM 4**
CLAIM 7
CLAIM 10

13. A method of detecting the presence or absence of antibodies in an animal or human, against a pathogenic mycobacteria in a sample which comprises:

- CLAIM 1**
- (a) providing a polypeptide according to ~~any one of claims 1 to 3~~ or a polypeptide which comprises a sequence selected from the sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or a polypeptide substantially homologous thereto, which comprises an epitope;
 - (b) incubating a biological sample with said polypeptide under conditions which allow for the formation of an antibody-antigen complex; and
 - (c) determining whether antibody-antigen complex comprising said polypeptide is formed.

14. A method of detecting the presence or absence of a polypeptide according to ~~any one of claims 1 to 3~~ or a polypeptide which comprises a sequence selected from the **CLAIM 1**

sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or a polypeptide substantially homologous thereto in a biological sample which method which comprises:

- (a) providing an antibody according to any one of claims 10 and 11;
- (b) incubating a biological sample with said antibody under conditions which allow for the formation of an antibody-antigen complex; and
- (c) determining whether antibody-antigen complex comprising said antibody is formed.

15. A method of detecting the presence or absence of cell mediated immune reactivity in an animal or human, to a polypeptide according to ~~claims 1 to 3~~ ^{claim 1} or a polypeptide which comprises a sequence selected from the sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or a polypeptide substantially homologous thereto, which method comprises

- (a) providing a polypeptide according to ~~any one of claims 1 to 3~~ ^{claim 1} or a polypeptide which comprises a sequence selected from the sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or a polypeptide substantially homologous thereto, which comprises an epitope;
- (b) incubating a cell sample with said polypeptide under conditions which allow for a cellular immune response such as release of cytokines or other mediator or reaction to occur; and
- (c) detecting the presence of said cytokine or mediator or cellular response in the incubate.

16. A pharmaceutical composition comprising a polypeptide according to ~~any one of claims 1 to 3~~ in a suitable carrier or diluent.

17. A composition according to claim 16 or a composition comprising a polypeptide which comprises a sequence selected from the sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or a polypeptide substantially homologous thereto,

for use in the treatment or prevention of diseases caused by mycobacteria.

18. A method of treating or preventing mycobacterial disease in an animal or human caused by mycobacteria which express a polypeptide according to ~~claims 1 to 3~~ **Claim 11** or a polypeptide which comprises a sequence selected from the sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or a polypeptide substantially homologous thereto, which method comprises vaccinating or treating an animal or human with an effective amount of said polypeptide.

19. A method of treating or preventing mycobacterial diseases in animals or humans caused by mycobacteria containing the polynucleotide of Seq.ID.No: 3 or 4, which method comprises vaccinating or treating an animal or human with an effective amount of a polynucleotide according to ~~claims 4 to 7~~ **Claim 4**, a vector according to claim 9 or a polynucleotide which encodes a polypeptide which comprises a sequence selected from the sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or a polypeptide substantially homologous thereto.

20. A method according to ~~claims 13 or 19~~ **Claim 18** for increasing the in vivo susceptibility of mycobacteria to antimicrobial drugs.

21. A normally pathogenic mycobacterium, whose pathogenicity is mediated in all or in part by the presence or the expression of a polypeptide as defined in ~~any one of claims 1 to 3~~ **Claim 1** or a polypeptide which comprises a sequence selected from the sequences of Seq.ID.No: 31, 33, 35, 37 and 39 or a polypeptide substantially homologous thereto, which mycobacterium harbours an attenuating mutation in a gene encoding one of the said polypeptides.

22. A vaccine comprising a mycobacterium as claimed in claim 21.

23. A vaccine according to claim 22 wherein the mycobacteria is selected from Mavs, Mptb and Mtb.